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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,210	01/26/2004	Noboru Yamaji	Q79353	6561
65565 7590 02/23/2007 SUGHRUE-265550 2100 PENNSYLVANIA AVE. NW WASHINGTON, DC 20037-3213			EXAMINER CROWDER, CHUN	
			ART UNIT 1644	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE 3 MONTHS			MAIL DATE 02/23/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/763,210

Applicant(s)

YAMAJI ET AL.

Examiner

Chun Crowder

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-17 is/are pending in the application.
- 4a) Of the above claim(s) 13-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicant's amendments, filed 11/22/2006, are acknowledged.

Claims 1-11 have been previously canceled.

Claim 12 has been amended.

Claims 12-17 are pending.

Claims 13-17 have been withdrawn from consideration, under 37 C.F.R. 1.142(b), as being drawn to nonelected inventions.

Claim 12 is currently under consideration as it reads on the originally elected invention of an antibody against a metalloprotease of SEQ ID NO:1.

2. This Office Action will be in response to applicant's arguments, filed 11/22/2006.

The rejections of record can be found in the previous Office Action, mailed 08/24/2006.

The text of those Sections of Title 35 U.S.C. not included in this Action can be found in a prior Action.

3. Applicant's amendment to the instant specification is acknowledged and has been entered.

4. Reference Declerck et al. (J.B.C., Vol. 270, No. 15, pp. 8397-8400) cited by applicant has been included in PTO-1449.

5. Claim 12 is rejected under **35 U.S.C. 103(a)** as being unpatentable over Kuno et al. (JBC 1997. 272;1:556-562) in view of Campbell (Monoclonal Antibody Technology. 1984. Published by Elsevier Science Publishers. Pages 1-32), Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan (J. Histochem. Cytochem. 1995; 43:881-886) for reasons of record.

Applicant's arguments in conjunction with the sequence alignment of hADAMTS1: 253-724, mADAMTS 1 : 254-725, rADAMTS 1 : 253-724, MDTS6 (the present invention): 213-682 and Declerck et al. (J.B.C., Vol. 270, No. 15, pp. 8397-8400) have been fully considered but have not been found persuasive.

Applicant argues that the relatively long amino acid sequence at which the reference and the claimed SEQ ID NO:1 match each other corresponds to the conserved sequence of the ADAMTSI in different species; as such, according to Declerck et al, antibodies cannot be generally produced against the highly conserved domains; Declerck et al. further teach in Table III on page 8399 that antiserum produced by immunizing a rabbit with the human antigen u-PA does not cross react with the mouse antigen u-PA that is 81% homologous to the human u-PA. Therefore, applicant asserts that the conventional method of making antibody will not be possible to produce an antibody that will cross react with ADAMTSI of different species.

This is not found persuasive for following reasons:

In contrast to applicant's assertions, the Declerck et al. clearly teach methods of making and using antibodies that cross-react to epitopes conserved across species by immunizing transgenic mice in which the expression of the target protein is abolished (knock-out) (see entire document, particularly right column on page 8397). Declerck et al. have produced a panel of monoclonal antibodies in t-PA knock-out mice that cross-react with antigen t-PA from other species including murine, rat, and human (e.g. see Discussion on pages 8399-8400).

Further, regarding applicant's assertion that Table II on page 8400 of the reference teach antiserum produced in rabbit using human antigen that does not cross react with murine antigen, it is noted that Declerck et al. teach that these data must be interpreted with caution because only a limited number of monoclonal antibodies are studied here and these monoclonal antibodies have been tested only using human antigen but not antigen from other species (e.g. see left column on page 8400).

Moreover, Declerck et al. concludes that immunization of any type of gene-inactivated mice with the respective knocked-out proteins could provide a general method to make unique monoclonal antibodies against structurally and functionally conserved domain within other protein families.

Given the teachings of Kuno et al. regarding the role of the isolated metalloproteinase, and the teachings of Campbell and Declerck et al. providing the method and advantages of making and using antibody, and Bost et al, and Bendayan regarding antibody cross-reactivity, the ordinary artisan at the time the invention was made would have had a reasonable expectation of success of producing the claimed antibody.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The rejections of record are maintained for the reasons of record, as they apply to the amended claim. The rejections of record are incorporated by reference herein as if reiterated in full.

6. Upon further consideration as well as applicant's amendments, the previous objection to the specification, rejections under 35 U.S.C. 112, first and second paragraphs and 35 U.S.C. 101 have been withdrawn.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.  
Patent Examiner  
February 9, 2007

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PRIMARY EXAMINER  
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2/12/07